

## REMARKS

Claims 11 – 44 are pending in the present application. Claim 11 has been amended, leaving Claims 11 – 44 for consideration upon entry of the present amendment. Support for the amendment to claim 11 can be found at least on page 14, paragraph [0062], lines 4 – 5 of the specification as filed. In the specification, it is stated that the polymer solution is mixed with the alkoxide solution. A phosphorus source and a calcium source are added to the mixture. The mixture is further reacted to form a sol solution.

### Claims Rejected under 35 U.S.C. § 102

Claims 11, 13 – 17, 21, 23, 24, 26 – 30, 32, 34, 36 and 37 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 6,294,041 to Boyce et al. (Boyce). (Office Action dated 02-21-08, page 2)

In making the rejection, the Examiner has stated that “[T]he implants of the Boyce patent are demineralized bone materials that have tri-calcium phosphate added as a filler material along with biocompatible polymers such as bioglass, starches, polyglycolide, polylactides and polymethylmethacrylate (Col.4, lines 25 – 35) (Office Action dated 02-21-08, page 7)

To anticipate a claim under 35 U.S.C. § 102, a single source must contain all of the elements of the claim. *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, 1768 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988).

Claim 11 as presently amended is directed to a bioactive glass composite, comprising a biocompatible polymer, a bioactive glass including at least one calcium, and at least one phosphorous molecular species; the biocompatible polymer being reacted with the bioactive glass.

Boyce teaches an osteoimplant fabricated from a solid aggregate of bone derived elements. (See Abstract) Boyce teaches that the osteoimplants comprise a solid aggregate of bone-derived elements having chemical linkages between their surface-exposed collagen molecules thus bonding adjacent bone elements to each other. (Col. 3, lines 50 – 53) Boyce teaches that the osteoplant can contain other components as listed below:

reinforcing particles, fibers, fillers, bone-growth inducing

substances, adhesives, plasticizers, flexibilizing agents, hydration facilitating agents, biostatic/biocidal agents, substances imparting radioopacity, metallic meshes and the like. Examples of reinforcing particles include fully mineralized cortical and cancellous bone, and partially demineralized cortical and cancellous bone in any form, including particles, sheets and shaped bone pieces; graphite or pyrolytic carbon. Examples of fillers include mineral material such as hydroxyapatite, tricalcium phosphate and other calcium salts, bone powder, fully mineralized and partially or fully demineralized cortical and cancellous bone in any form, including particles such as demineralized bone powder (or "demineralized bone matrix" as it may also be called) sheets and shaped bone pieces, graphite or pyrolytic carbon, bioglass or other bioceramic or natural or synthetic polymers, e.g., bioabsorbable polymers such as polyglycolide, polylactide, glycolide-lactide copolymer, and the like, and nonbioabsorbable materials such as starches, polymethyl methacrylate, polytetrafluoroethylene, polyurethane, polyethylene and nylon. Suitable plasticizers, flexibilizing agents and hydration facilitating agents, include liquid polyhydroxy compounds such as glycerol, monacetin, diacetin, and mixtures thereof. Suitable biostatic/biocidal agents include antibiotics, povidone, sugars, and mixtures thereof; suitable surface agents include the biocompatible nonionic, cationic, anionic and amphoteric surfactants, and mixtures thereof.

(Col. 4, lines 14 – 43)

In the first instance, Boyce does not teach a bioactive glass including at least one calcium, and at least one phosphorous molecular species. As noted above, Boyce teaches that the osteoplant can comprise reinforcing fillers, examples of which are tricalcium phosphate or bioglass. There is no evidence in Boyce that the bioglass was ever mixed with the calcium and phosphate. More specifically, Boyce does not teach that the glass contains the calcium and the phosphorus as presently claimed. Boyce therefore does not teach all elements of the claimed invention and therefore cannot anticipate the claimed invention.

In addition, Boyce does not teach the invention with any degree of specificity as required by law. Boyce provides a long laundry list of reinforcing agents, but does not specifically state that the glass is mixed with calcium or phosphate. In this regard the courts have held that “[A] reference must provide a disclosure with “sufficient

specificity” to constitute a description of the claimed composition within the purview of 35 U.S.C. § 102(b).” *In re Schaumann*, 572 F.2d 312, 315, 197 USPQ 5, 8 (CCPA 1978). For both of these reasons, Boyce cannot anticipate the claimed invention. Applicants respectfully request the Examiner to withdraw the rejection and allow the claims.

Claims 11 - 14, 26, 27, 28, 30, 31, and 34 - 36 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 6,027,742 to Lee et al. (Lee). (Office Action dated 02-21-08, page 3)

In making the rejection, the Examiner has stated that

The Lee patent discloses a bioresorbable polymer implant with low crystallinity, calcium phosphate and a supplementary material (abstract). The supplemental materials include biocompatible polymers such as bio active glass compositions including calcium, silicon and phosphorous oxide (Col. 9, lines 55 – 63) and polyglycolide polymers (Col. 9, lines 40 – 55). These disclosures meet the limitations of the claims.

(Office Action dated 02-21-08, pages 7 and 8)

Lee teaches a composite material including a strongly bioresorbable, poorly crystalline apatitic calcium phosphate composite and a supplementary material. (see Abstract) Lee teaches that the ceramic composite material contains a nano-size, poorly crystalline apatitic calcium phosphate solids with Ca/P ratios comparable to naturally occurring bone minerals and having stiffness and fracture toughness similar to natural bone. (see col. 4, lines 47 – 51) The composite further contains a supplemental material in an amount effective to impart a selected characteristic to the composite. (Col. 5, line 4 – 6)

Lee provides a long list of supplemental materials that can be added to the crystalline apatitic calcium phosphate, but does not teach a composition that contains a polymer and a glass that contains calcium and phosphorus moieties. The list of supplemental materials along with the associated text are reproduced below:

By way of example only, suitable bioerodible polymers for use as a matrix in the composite include, but are not limited to, collagen, glycogen, chitin, celluloses, starch, keratins, silk, nucleic acids, demineralized bone matrix, derivativized hyaluronic acid, polyanhydrides, polyorthoesters, polyglycolic acid, polylactic acid,

and copolymers thereof. In particular, polyesters of  $\alpha$ -hydroxycarboxylic acids, such as poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), and polyanhydrides, such as poly(anhydride-co-imide) and co-polymers thereof are known to bioerode and are suitable for use in the present invention. In addition, bioactive glass compositions, such as compositions including  $\text{SiO}_2$ ,  $\text{Na}_2\text{O}$ ,  $\text{CaO}$ ,  $\text{P}_2\text{O}_5$ ,  $\text{Al}_2\text{O}_3$  and/or  $\text{CaF}_2$ , may be used in combination with the PCA calcium phosphate of the invention.

(Col. 9, lines 45 – 61)

As can be seen in the paragraph above, Lee teaches that polymeric supplemental materials can be added to the crystalline apatitic calcium phosphate, or bioactive glass compositions can be added to the crystalline apatitic calcium phosphate. Lee does not teach that both the polymer and the bioactive glass are added to the calcium phosphate. In addition, Lee does not specifically teach the mixing of a glass that contains calcium and phosphate with a polymer. Applicants therefore believe that the Lee does not teach all elements of the claimed invention and therefore cannot anticipate the claimed invention. Applicants respectfully request the Examiner to withdraw the rejection and allow the claims.

Claims 11, 12, 17 – 19, 30, 33, 36 and 37 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,990,380 to Marotta et al. (Marotta). (Office Action dated 02-21-08, page 3)

Marotta teaches percutaneous implants including a portion implantable into a patient, a dermal bonding region capable of forming a bond between the implant and a dermal layer of the patient after the implantable portion is implanted into the patient. (see Abstract) Marotta teaches that the implants contain a bioactive glass made from 30-95%  $\text{SiO}_2$ , 0-35%  $\text{CaO}$ , 0-35%  $\text{Na}_2\text{O}$ , and 0-15%  $\text{P}_2\text{O}_5$ . (see Claim 4) Marotta teaches that the bioactive glass is embedded in a silicone elastomer. (see Col. 4, lines 48 – 55) Marotta however does not teach that the bioactive glass is reacted to the silicone polymer as presently claimed. Applicants therefore believe that Marotta does not teach all elements of the claimed invention and therefore cannot anticipate the claimed invention.

Applicants respectfully request the Examiner to withdraw the rejection and allow the claims.

Claims 11 - 13, 21, 22 and 25 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,676,720 to Ducheyne et al. (Ducheyne). (Office Action dated 02-21-08, page 4)

Ducheyne teaches a glass material that is formed from SiO<sub>2</sub>, CaO, Na<sub>2</sub>O and P<sub>2</sub>O<sub>5</sub>. (see Abstract) Ducheyne teaches mixing the glass material with polyvinyl alcohol to form a slurry. (see Claim 7) Ducheyne, like Marotta, does not teach that the glass material is reacted to the polyvinyl alcohol as presently claimed. Applicants therefore believe that Ducheyne does not teach all elements of the claimed invention and therefore cannot anticipate the claimed invention. Applicants respectfully request the Examiner to withdraw the rejection and allow the claims.

Claims 11 and 39 - 44 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent Application No. 20010016353 to Janas et al. (Janas). (Office Action dated 02-21-08, page 4)

Janas teaches using an organic polymeric material as a template and impregnating the organic polymeric material with a calcium phosphate precursor solution and then sintering the impregnated polymer to form a bioresorbable ceramic structure that contains calcium and phosphate. (see page 3, paragraphs [0029] and [0030]) Janas thus teaches a polymer that is saturated with calcium and phosphorus precursors, but does not teach a glass that contains calcium and phosphorus moieties as presently claimed. More specifically Janas does not teach a polymer that is reacted with a glass that contains a calcium moiety and a phosphate moiety as presently claimed. Applicants therefore believe that Janas does not teach all elements of the claimed invention and therefore cannot anticipate the claimed invention. Applicants respectfully request the Examiner to withdraw the rejection and allow the claims.

Claims 11, 20 and 36 – 38 are rejected under 35 U.S.C. §102 (a, e) as being anticipated by U.S. Patent No. 6,344,496 to Niedrauer et al. (Niedrauer). (Office Action

dated 02-21-08, page 5)

Niedrauer teaches blending bioactive ceramics (e.g., BIOGLASS) with a biodegradable polymer. (see Col. 3, lines 10 – 15) Niedrauer teaches that the surface of the bioactive ceramic is passivated, i.e., it is rendered incapable of reacting with water. (Col. 4, lines 43 – 48) Niedrauer thus does not teach that the glass is reacted with the polymer.

In addition, while Niedrauer teaches the use of bioactive ceramics, it does not teach a glass that contains both calcium and phosphorus as presently claimed. Indeed the term “phosphorus” is not mentioned in the brief summary of the invention or in the detailed description of Niedrauer. Applicants therefore believe that Niedrauer does not teach all elements of the claimed invention and therefore cannot anticipate the claimed invention. Applicants respectfully request the Examiner to withdraw the rejection and allow the claims.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Assignee.

Respectfully submitted,

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